IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Brian A. Rosenfeld, M.D. and Michael Breslow, M.D.

Serial No.:	09/443,072	Group Art Unit:	2167
Filed:	11/18/99	Examiner:	Harle, J.

For: SYSTEM AND METHOD FOR PROVIDING CONTINUOUS, EXPERT NETWORK CRITICAL CARE SERVICES FROM A REMOTE LOCATION(S)

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AFFIDAVIT BY DR. MERVYN MAZE

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I, Dr. Mervyn Maze, residing in London, UK, state as follows:

1. I obtained my M.B., Ch. B. degree in Medicine in 1970 from University of Cape Town.

2. My experience includes thirty-one (31) years in Intensive Care Medicine in Cape Town, London and Stanford.

3. My Curriculum Vitae is attached to provide further information regarding my background and qualifications that allow me to make the statements contained herein.

4. I have read and reviewed Patent Application Serial No.: 09/443,072 and the attached amended claim set.

5. I have read and reviewed the attached article "Intensive care unit telemedicine: Alternate paradigm for providing continuous care" from *Critical Care Medicine* 2000 Vol. 28, No. 12 by Rosenfeld et al.(the "Rosenfeld Study") describing the clinical study for which Dr. Rosenfeld was the Principal Investigator. I am familiar with the procedures described in this paper.

6. I believe the claimed invention is materially different from the Rosenfeld Study for at least the following reasons:

   - The claimed invention provides centralized monitoring of a plurality of geographically disparate ICUs by intensivists. In contrast, the Rosenfeld Study monitored only

one single specialty 10-bed ICU. It is the capability of the claimed invention to allow a physician-lead team, made up of intensive care specialists, critical care nurses and clerical support personnel (care team), to care for patients in multiple ICU's in disparate geographic locations, either within a building or in different buildings, simultaneously that creates new efficiencies and offers the potential to change the care paradigm for ICU patients. Thus, the expertise of the entire care team is leveraged over many ICU patients, who could not otherwise (without the claimed invention) be cared for by a single team.

- In contrast to the Rosenfeld Study where a single intensivist monitored faxed information, or initiated communication to view a single patient's bedside monitor over a personal computer, the claimed invention uses a computerized patient care management system that feeds key clinical information on multiple ICU patients simultaneously to the remote monitoring care team. The claimed invention includes imbedded decision support algorithms that further assist the care team in the continuous monitoring of large numbers of ICU patients. The claimed invention analyzes simultaneously all incoming patient physiologic data (from bedside monitors) and laboratory data and provides visual alarms for the care team that alerts them care to detrimental trends in patient vital signs and/or laboratory values of which the care team might not otherwise be aware of. These features of the claimed invention allow a single physician-led team to care for patients in multiple, geographically disparate sites simultaneously. These features are totally lacking from the Rosenfeld Study and are not suggested by the study in any way.

- The claimed invention provides for 24-hour dedicated monitoring/management by a care team. The care team provides this service from a dedicated monitoring facility comprising equipment and decision support algorithms developed explicitly for this purpose. The claimed invention provides for automated warnings relating to vital signs and trends in vital signs, provides assessment of those trends for the intensivist, and makes recommendations for intervention available for consideration by the intensivist. The care team has no other care responsibilities during the time it is monitoring/managing the multiple geographically disparate ICU(s). The attention of the care team is devoted to the ICU patients and only the ICU patients.

- In contrast to the present invention, the Rosenfeld Study provided only 4-5 hours of ad hoc monitoring by a single intensivist from the intensivist's home (i.e. no continuous monitoring, no support personnel, no dedicated facility). Further, the intensivist monitoring was not triggered in any automated way by any form of decision support algorithms, but was conducted periodically by the intensivist, as he deemed fit and time permitted. The intensivist in the Rosenfeld Study was solely responsible for analyzing the data, deducing trends in the patient's vital signs, assessing the meaning of the trends and, deciding on the corrective action to be taken - without access to any software tools to assist in these tasks. The software tools in the claimed invention create efficiencies that enable a single, intensivist-led team to monitor and care for large numbers of ICU patients.

7. I believe that remote, 24-hour intensivist-lead care team monitoring of ICU patients in multiple geographically disparate locations is not taught by the Rosenfeld Study nor would one of skill in the art make the required changes to the equipment and procedures of the Rosenfeld Study to arrive at the present invention for at least the following reasons:

- Remote monitoring and direct intervention of ICU patients is contrary to prior accepted practice, where physicians are physically present in the ICU.

- The generally accepted medical monitoring paradigm in ICU's with intensivists on-staff is for the intensivists to conduct rounds with the staff, and for ICU nurses and other physicians to notify the intensivists of emergencies on an as-needed basis. The Rosenfeld Study subscribed to this generally accepted model of intensivist deployment in ICU's, daily rounds, periodic monitoring, and responding to requests for assistance from on-site personnel.

- The monitoring paradigm presently employed by hospitals is having lower-skilled bedside nurses perform this function. These personnel, with only bedside patient monitoring equipment and visual inspection, are relied on to make the decision to contact specialists, such as intensivists, when problems are detected.

- The invention described and claimed in Application Serial No.: 09/443,072 does not rely on the paradigm of primary monitoring by bedside personnel, with secondary calls to intensivists, but rather has the off-site intensivist-lead care team provide continuous, 24-hour monitoring. The care team is capable of unilaterally entering the patient room for video and audio communication, is supported by decision support algorithms that automatically alert the intensivist to detrimental trends in a patients' vital signs and facilitate the intensivist contacting the lower-skilled on-site personnel when interventions are necessary. Although the Rosenfeld Study included intensivist-initiated intervention through on-site physicians, the lack of 24-hour continuous monitoring illustrates that the prior art monitoring paradigm was still considered valid by those in the Rosenfeld Study.

- The Rosenfeld Study disclosed nothing of the technological nature disclosed in the claimed invention. Indeed the only way the intensivist had contact with the ICU and/or patient data was for the intensivist to intermittently conduct active dial-up direct monitoring of the real-time bedside waveforms, request information by fax machine, or to telephonically contact an ICU nurse and have equipment (such as a video camera) physically moved to the desired patient location. None of this activity was in response to any system of automated notification to the intensivist and most required actions by on-site personnel.

- The technology tools that were developed in the current invention, such a smart alarms and physiologic data trend analysis, instantly available video monitoring from permanent camera installations in each ICU room, and comprehensive data links to the command center, were not available at the time of the original clinical study nor was their use suggested in any way.

- The initial clinical study never addressed the potential for a single monitoring site for overseeing the care of patients in multiple ICU's, thereby leveraging the expertise of an intensivist over a number of ICU's in geographically disparate locations.

- The original trial technology suite could not have been used over multiple ICU's in different geographic locations.

- At the time the clinical study it was unprecedented to have an intensivist functioning in a dedicated monitoring capacity and NOT attending to other functions.

- During the Rosenfeld study, an intensivist was required to monitor, on an ad hoc basis, over a 24-hour shift. Continuous monitoring over such a long time period is too physically and mentally taxing to be feasible. In contrast, the system of the current invention allows for constant monitoring by an intensivist-led care team functioning on a normal 6-12 hour shift thereby alleviating both the physical and mental stress associated with a 24-hour shift.

- The Rosenfeld study was not the same model as that used in the present invention's model. The functioning of the current system constitutes an entirely different manner of monitoring multiple, geographically disparate ICU's than the clinical study which monitored but a single ICU without the analytical support offered in the present invention system.

- For a variety of licensing and clinical reasons, the clinical study was not a feasible model for hospitals to use for ICU care. Individual hospitals would not have established intensivists at remote locations to monitor a single ICU at the hospital, having only the technology described in the study as a supporting infrastructure.

- When compared to the prior standard of care, that is, an on-call intensivist responding to calls from on-site nurses, the results of using the present invention are remarkable, resulting in far better outcomes for ICU patients and far earlier intervention in life-threatening trends.

8. I believe that providing either a computerized patient care management system or a set of decision support algorithms to a remote care team (or a combination thereof) is not taught by the Rosenfeld Study, and neither the paper nor the standard practices of the time would suggest such a modification for at least the following reasons:

    - The use of computerized patient care management systems at the time of the invention was limited, even in major hospitals, to the recording of patient data for later review by physicians, and to isolated on-site systems that sound an audible alarm when an extreme condition in a patient's vital signs is reached (i.e. cardiac arrest). Further, computerized decision support algorithms in the medical community were not available.

- When computerized patient care management systems are deployed by hospitals, they are provided at the bedside or ICU nursing stations. They are not provided remotely to a physician. Instead, physicians are contacted by a bedside nurse (via a "pager") to inform them that a problem has developed.

- Since the accepted wisdom of the medical community is to deploy patient care management systems and/or paper-based decision support for lower-skilled medical care givers on-site, there would be no reason to deploy these systems at a remote site for a care giver having the higher-skills of an intensivist.

9. The Rosenfeld Study evaluated the potential of "currently available technology" to "extend the effective reach of intensivists," but failed to disclose or suggest any of the additional technology of the presently claimed invention, such as (i) intensivist access to patient care management systems and/or decision support algorithms, that are required to effectively scale the monitoring to a greater number of patients and (ii) central command center monitoring that is required to effect a viable remote ICU monitoring model, (iii) monitoring of a plurality of geographically disparate healthcare locations/ICUs from a single remote command center, (iv) the use of a care team to enable monitoring and intervention on multiple patients in geographically different locations and (v) a data server/data warehouse for storing and analyzing data.

Date: October 3, 2002

M. MAZE, M.D.
Title Professor, Chair, Anesthesia and Intensive C
Affiliation Imperial College, London

WITNESS MY HAND and seal this 4th day of October, 2002.

PETER BARNES
Type Name Here

STATE OF London)
) ss:
COUNTY OF UK)

On this ____ day of _____, 2002 personally appeared before me _____ to me known, and known by me to be the same person described in and who executed the foregoing instrument, and acknowledged that he executed the same, of his own free will and for the purposes set forth.

Notary Public

My Commission Expires: September 2004 in UK.

CURRICULUM VITAE

MERVYN MAZE, M.B. Ch.B., F.R.C.P.
Chair, Department of Anaesthesia and Intensive Care
Faculty of Medicine, Imperial College, London, UK

Date of Birth : July 11, 1947
Place of Birth: Cape Town, Republic of South Africa
Citizenship: United States
Social Security: 558-41-6848
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Education:

1965-1970	Bachelor of Medicine, Bachelor of Surgery (M.B. Ch.B.), University of Cape Town, South Africa. Degree conferred with honors
1973 (Mar)	Member of the Royal College of Physicians, UK (M.R.C.P.,U.K.),
1982 (Apr)	Certified by the American Board of Anesthesiology
1996	Fellow of the Royal College of Physicians, UK (F.R.C.P.)
1999	Fellow of the Royal College of Anaesthetists, UK (F.R.C.A.)
2002	Fellow of the Academy of Medical Sciences (FMedSci)

Postgraduate Education and Professional Experience

1971	Resident Medical Officer (Intern), Groote Schuur Hospital, Cape Town, South Africa
1972	Senior House Officer, Department of Medicine, Groote Schuur Hospital, e Cape Town, Sout Africa
1973-1976	Registrar, Professorial Department of Medicine, Royal Free Hospital, London
1976-1979	Postdoctoral Research Fellow, Department of Medicine, Stanford University
1979-1981	Resident, Department of Anesthesia, Stanford University
1981-1987	Assistant Professor, Department of Anesthesia, Stanford University
1/1/88-11/94	Associate Professor, Department of Anesthesia, Stanford University
12/94 -1999	Professor, Department of Anesthesia, Stanford University
1981-1999	Staff Physician, Veterans Affairs, Palo Alto Health Care System
1987 -1999	Neuroscience Graduate Program, Stanford University
1995- 1997	Director of Research, Department of Anesthesia, Stanford University
1997-1999	Associate Chair for Research, Department of Anesthesia, Stanford University
1999-Present	Sir Ivan Magill Professor of Anaesthetics, Imperial College
2000-Present	Head, Department of Anaesthetics and Intensive Care, Imperial College
2000-Present	Vice Chair, Division of Surgery, Anaesthetics and Intensive Care, Imperial College
2001-Present	Director, Research and Development, Chelsea and Westminster Hospital, London, UK
2002- Present	Director, Multi-Disciplinary Education Training and Research, Chelsea and Westminste Hospital, London, UK
2002- Present	Campus Dean for the Chelsea and Westminster Hospital Site, Imperial College, London

Research Support

National Institutes of Health

1977	NIH Membrane Pathology Postdoctoral Research Fellowship #5732 GM 07026-03;	Trainee
1978	NIH Postdoctoral Research Fellowship #1F32 AM 05987-01;	Trainee
1981-1983	NIH New Investigator Research Award #1R23 GM 30232 Catecholamine Halothane Interactions during anesthesia	Principal Investigator
1982	NIH Biomedical Research Support Grant, #2507-RR5353-20 Adrenergic function and cardiopulmonary bypass	Principal Investigator
1983-1993	NIH # R01 GM 30232 Adrenergic Actions During Anesthesia With Volatile Agents	Principal Investigator
1993-2002	NIH # R01 GM 30232 Actions Of Alpha-2 Adrenergic Agonists In Anesthesia	Principal Investigator
1998-2003	NIH# RO1 GM 57545 Mechanisms for tolerance to Actions of alpha-2 agonists	Principal Investigator

Department of Veterans Affairs

1981-1983	RAG; Myocardial sensitization by halothane to exogenous catecholamines	Principal Investigator
1988-2004	VA Merit Review; Functional effects of anesthesia on the adrenergic nervous system	Principal Investigator
1989-1992	VA-DOD Collaborative Project; Perioperative use of clonidine as an adjunctive anesthetic agent	Co-Principal Investigator

Other Non-Federal Funding

1987-1989	International Anesthesia Research Society - BB Sankey Award; Anesthetic depth and and central monoaminergic neurotransmission	Principal Investigator
1987-1988	American Cancer Society; Sympathetic nervous system in a rat model of pheochromocytoma	Principal Investigator
1986	American Heart Association, California Affiliate, Grant-in-aid 86N133	Principal Investigator

United Kingdom

1999-2004	MRC Programme Grant; Endogenous and Exogenous actions of alpha-2 agonists in Anaesthesia and Analgesia	Principal Investigator
2000-2005	MRC Co-operative Group Grant; General Anaesthesia and Neuronal Excitability	Co-Principal Investigator
2000-2001	JIF Award; General Anaesthesia: from Molecular Actions to Neuronal Pathways	Co-Principal Investigator
2001-2003	MRC Clinical Trial; A clinical trial as proof of principal of the analgesic effectiveness of cannabinoids on post-operative pain	Co-Principal Investigator

Professional Activities

Departmental

1981-1990	Resident's Education Committee, Stanford University
1987-1999	Appointment and Promotions Committee, Stanford University
1995 - 1999	Research Committee, Stanford University

University and Hospital

1982-Present	Well-Being of Physicians ; Stanford Health Services
1985-1995	Animal Care and Use Committee, Veterans Affairs Hospital
1988-1992	Minority Admissions Advisory Panel, Stanford University
1992-1999	Medical School Admission Committee, Stanford University
1992-1999	South African Faculty Initiative Committee, Stanford University
1996- 1999	Laboratory Safety Committee, Stanford University
2001-Present	Finance Committee, Faculty of Medicine, Imperial College
2001-Present	Research Committee, Faculty of Medicine, Imperial College
2001-Present	NHS-Imperial College Liaison Group
2002- Present	Principal's Advisory Group

National

1988-1992	Scientific Advisory Board, Association of University Anesthesiologists
1988-1992	Associate Editor, Anesthesiology
1995 - 1998	Councillor, Association of University Anesthesiologists
1995-1999	Associate Editor, Anesthesiology
1999-present	Editor, Anesthesiology

Current Membership in Professional Societies

California Society of Anesthesiologists
International Anesthesia Research Society
American Society of Anesthesiologists
California Medical Association
Association of University Anesthesiologists
American Association for the Advancement of Science
Society for Neuroscience

Research Trainees

Undergraduate - 22
Medical Students - 23
Postdoctoral Fellows - 20
Ph.D Students - 5

BIBLIOGRAPHY

Scientific Articles

1. Maze M, Novis BH, Lurie BB: Involuntary muscle involvement in dystrophia myotonica. S African Med J 47:1947-1950, 1973.

2. Maze M, Novis BH, Lurie BB, Bank S: Involuntary muscle involvement in dystrophia Myotonica. Case report. S Afr Med J 47; 1947-50, 1973

3. James O, Wood J, Maze M, Gayotto LC, Williams HS, Sherlock S: Proceedings: 67Ga citrate liver scanning: evaluation of its use in 80 patients and evidence of intrahepatic distribution by autoradiography. Gut 15: 342, 1974.

4. Maze M, Wood JJ: 67Ga-uptake in liver lesions. J Nuclear Med 16:442-443, 1975

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6. Agnew J, Maze M: Clinical trial of four pancreatic scanning agents. Br J Radiol 51:206-209, 1978.

7. Maze M, Gray GM: Intestinal brush border amino-oligopeptidases: Cytosol precursors of the membrane enzyme. Biochemistry 19:2351-2358, 1980.

8. Samuels SI, Maze M: Beta-receptor blockade following the use of eye drops. Anesthesiology 52:369-379, 1980.

9. Maze M: Clinical implications of membrane receptor function in anesthesia. Anesthesiology 55:160-171, 1981.

10. Scott J, Maze M, Peters TJ: Prednisolone enhances aminopeptidase turnover in the adult rat small intestine. Biochim Biophys Acta 719:464-473, 1982.

11. Maze M, Smith CM: Identification of receptor mechanism mediating epinephrine-induced arrhythmias during halothane anesthesia in the dog. Anesthesiology 59:322-326, 1983

12. Maze M, Mason DM, Kates RE: Verapamil decreases MAC for halothane in dogs. Anesthesiology 59:327-329, 1983.

13. Maze M, Mason DM: Etiology and treatment of halothane-induced arrhythmias. Clinics in Anaesthesiology 1:301-322, 1983.

14. Spiss CK, Smith CM, Maze M: Alpha-adrenergic responsiveness correlates with epinephrine dose for arrhythmias during halothane anesthesia in dogs. Anesth Analg 63:297-300, 1984.

15. Berry AJ, Isaacson IL, Kane MA, Shatz GC, Bastron RD, Maze M, Spiss CK, Rizk SK, Ronai AK, Kimovec MA: Multicenter study of the prevalence of hepatitis B viral serologic markers in anesthesia personnel. Anesth Analg 63:738-742, 1984.

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18. Spiss CK, Smith CM, Tsujimoto G, Hoffman BB, Maze M: Prolonged hyporesponsiveness of vascular smooth muscle contraction after halothane anesthesia in rabbits. Anesth Analg 64:1-6, 1985.

19. Maze M, Smith CM, Baden JM: Halothane anesthesia does not exacerbate hepatic dysfunction in cirrhotic rats. Anesthesiology 62:1-5, 1985.

20. Metz S, Maze M: Halothane concentration does not alter the threshold for epinephrine-induced arrhythmias in dogs. Anesthesiology 62:470-474, 1985.

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22. Gaba DM, Metz S, Maze M: Post-countershock myocardial damage after pretreatment with adrenergic and calcium channel antagonists in halothane-anesthetized dogs. Anesthesiology 62:610-614, 1985.

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26. Maze M, Spiss CK, Tsujimoto G, Hoffman BB: Epinephrine infusion induces hyporesponsiveness of vascular smooth muscle. Life Sci 37:1571-1578, 1985.

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45. Maze M, Segal IS, Bloor BC: Clonidine and other alpha-2 adrenergic agonists. Journal of Clinical Anesthesia 1:149-157, 1989

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